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## **Biodegradable plates and screws in oral and maxillofacial surgery**

Buijs, Gerrit Jacob

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CHAPTER 1

GENERAL  
INTRODUCTION



## GENERAL INTRODUCTION

### Field of interest

Traumatic injuries in the maxillofacial region and dentofacial anomalies may have considerable physical and psychological impact on patients. Therefore, major efforts should be carried out to anatomically and aesthetically restore form and function of the maxillofacial hard and soft tissues in such cases (6). The maxillofacial skeleton consists of 3 parts: the cranium, the mid-face, and the mandible. The mandible articulates with the base of the skull at the left and right temporomandibular joint and at the level of the dental occlusion, and is powered by forceful masticatory muscles. This biomechanical system allows people to perform important functions, such as chewing, swallowing, laughing, and speaking. Physically, the mandible is a heavily loaded bony structure and, consequently, its cortex is thick and compact. By contrast, the mid-face consists of thin-walled cavities, strengthened by bony buttresses absorbing forces exerted through the muscles of the maxillofacial skeleton (7).

The diagnosis and treatment of facial fractures and dentofacial anomalies play a prominent role within oral and maxillofacial surgery. Through population growth, increase of traffic, industrialization, violence and sport, the field of traumatology has considerably increased. Today, of the fractures, approximately 55% are caused by traffic accidents, 20% by accidental falls, and 17% by assaults (8). The wearing of helmets and seatbelts and the general introduction of airbags in automobiles were major steps forward in the prevention of trauma. In general, good clinical results are currently achieved in both maxillofacial traumatology and dentofacial orthopedics primarily because of advanced diagnostic radiographic methods as well as refined surgical techniques and fixation materials.

### Diagnostic radiographic methods

Diagnostic radiographic methods are essential (1) to determine the exact extent of suspected maxillofacial fractures, and (2) for the diagnosis and treatment planning of osteotomies. Three-dimensional (3D) visualization of the bony skeleton and the dentition can be obtained by Computed Tomography (CT) and is the golden standard for fractures. The images are very precise and the surgeon can determine preoperatively where the plates and screws should be placed to acquire immobilization of the bone fragments. A disadvantage of CT examination is the relatively high radiation exposure. Recently, Cone Beam Computed Tomography (CBCT) has been developed, which is faster and produces less radiation (9). Conventional images, such as a panoramic radiograph and a fronto-suboccipito radiograph, are the standard recordings to assess mandibular fractures. In case of (para)median fractures, axial radiograph may provide additional information. A panoramic radiograph and a lateral cephalogram are the standard radiographs for osteotomies of the mandible and maxilla.

### Requirements for adequate bone healing

Essential aspects for bone healing of fractures and osteotomies are sufficient vascularization, anatomical reduction, and immobilization of bone segments (7;10). The treatment of nearly all maxillofacial fractures and osteotomies is currently performed by an open surgical approach to have a better control of the (re)positioning of bone fragments (6;11). Immobilization is obtained using fixation plates and screws. Various compressive, tensile, and torsion forces need to be counteracted by the plates and screws at the fracture crevice and the osteotomy site. After most of the mandibular fractures, the bone takes over compressive forces, whereas the osteosynthesis devices counteract the lost tensile forces. This is called load sharing between the bone and the plates and screws. In case of bony defects, comminuted fractures and bi-lateral sagittal split osteotomies, a plate is fully loaded for bending forces and is called load bearing. Load sharing allows plate and screw dimensions that are much smaller than those necessary for load bearing. The next sections comprise a review of the development of different fixation systems used for immobilization.

### Refined surgical techniques and development of fixation material

**Closed fracture management** – In the first half of the past century maxillofacial trauma were predominantly treated in a closed (i.e. non-surgical) manner. Immobilization of bone segments was achieved with InterMaxillary Fixation (IMF) in most cases. Stainless steel ligatures were tied up along the dental arches so that the correct dental occlusion could be achieved, whereas in more difficult cases the upper or the lower jaw could additionally serve as a template. Sophisticated external frame fixation devices were applied to achieve immobilization in severe multi-fragment situations (12). An external frame was usually secured with plaster of Paris, bandages or plastic head caps (13). Figure 1. Man with fixation 'apparatus' fixed with plaster of Paris. These devices were generally uncomfortable, patient-unfriendly and had a rather gruesome appearance (6;13). They immobilize the temporomandibular joints resulting in cartilage degeneration. Moreover, the requirements for optimal bone healing could not be acquired. For example, fractures and osteotomies above the Le Fort I level were difficult to immobilize with these external devices (6). The transfer pins from the bone segments to the external fixtures facilitate an easy entry of bacteria to the healing bone. Treatment without an open intervention impedes surgeons to anatomically re-position the bone segments.

**Figure 1.** Man with fixation 'apparatus' fixed with plaster of Paris

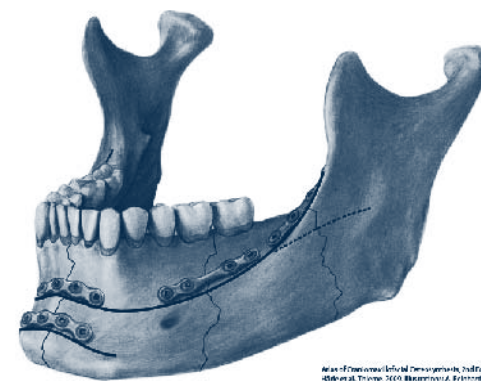


**Open fracture management** – In the second half of the past century there was a shift from closed to open surgical treatment. Besides the improved anaesthetic techniques and infection control, especially the development of the so-called training- or function-stable fixation materials, was responsible for this shift. Training-stable means 'moving without loading' whereas function-stable means 'moving and loading'.

Starting with wire osteosynthesis, surgeons made bur holes through both bone fragments after careful stripping of the periostium. Subsequently, a wire was tied up through the bur holes and the ends were twisted along each other (14). Due to the open fracture management, there was a better control of repositioning the dislocated fragments (6). The fragments could better be stabilized with wire osteosynthesis compared to external fixation devices. Nonetheless, wire osteosynthesis were not able to optimally stabilize bone fragments in order to acquire training- of even function-stable fixation. The first fixation systems that obtained sufficient stability to immediately restore the functions of the maxillofacial skeleton were developed in 1957 by the "Arbeitsgemeinschaft für Osteosynthese fragen" (AO), a Swiss study group. This study group used the ideas of the fixation of fractures of the long bones published by Danis in 1947 (15). The emergence of these plates and screws heralded, in the 60s of last century, the era of training- and function-stable osteosynthesis system. With these systems fracture fragments could anatomically be stabilized and held in position, and could be directly and functionally loaded. With these plates and screws, it was possible to obtain a certain stress on the fracture segments against each other. Because of this stress, the fracture crevice obtained a resistance to friction and mobility. This so-called compression system was later ingeniously built into the screw holes of the plates, where the screw heads, with eccentric screw placement, could build up the required axial interfragmental compression between the bone fragments. These plates are called dynamic compression plates, or DCP plates (16-18). During the healing period, stability of the fracture is maintained for approximately 6 to 8 weeks. The acquired compression does not lead to bone necrosis, whereas the remodelling of the bone compensates for the instability that might arise from the gradual decrease of the compression. When using this type of fixation, the formation of callus, estimated as a sign of lack of stability could be prevented. Initially, plates for application in the lower jaw with bicortical screws were developed to achieve the desired stability analogous to the fixation of fractures in long bones (19-21). Given the choice for bicortical anchoring of the screws and in order to avoid damage to the roots of the teeth and nerve structures, the only safe place for these systems was the lower border of the mandible. In terms of mechanical stress, this was the most demanding and the least favourable position to compensate dislocating forces. Often, these plates were applied via an extra-oral approach and required a disadvantageous large skin incision and wide stripping of the periostium to insert and apply the voluminous plates. An advantage of these relatively large and bulky plates was that they were strong enough to bridge bony defects, bone grafts, and comminute fractures used for reconstructions. Late in the 70s, a mini-plate system for the mandible was introduced by Champy et. al. (22;23). These small plates have much smaller dimensions than the AO-plates that were used for the fixation of fractures of the facial skeleton. The system was derived from the 'midface' fixation system launched by Michelet in 1973 (24). The size of the mini-plates was adapted to a mechanically more favourable location for fixation of mandibular fractures (Figure 1).

The plates and screws were relatively small and the plates were easier to bend. With delicate intra-oral incisions, bone segments could be visualized so that they could be repositioned anatomically while the plate could be easily inserted and gently adapted to the curvature of the maxillofacial bones. Subsequently, the screws could be inserted mono-

**Figure 2.** Favourable location of plates and screws on the mandible



cortically, leading to a firm stabilization. In this way, bone segments, even of complicated fractures and of osteotomies, could be accurately stabilized (25).

Using this system, all (dislocated) mandibular fractures can be stabilized in a 'training-stable' way with the exception of fractures involving a defect to be bridged (26). This simpler technique, as well as the benefits of an intraoral approach, meant a shift in the preference of surgical treatment of mandibular fractures in favour of the mini-plate method (27). Initially, the appearance of the mini-plate method led to a fundamental discussion of the proponents of the bicortical fixed plates obtaining absolute stability (function stable fixation) and the advocates of mono-cortically fixed mini-plates (training stable fixation). The latter were convinced that with less material on mechanically favourable locations, an adequate fixation of the fracture segments followed by undisturbed fracture healing could be achieved. Research has now shown that undisturbed healing can be achieved with both methods, provided that appropriate repositioning (i.e. anatomical reduction) of the fracture parts is combined with sufficient plate material in strength and number. By increasing the complexity of the fracture, more plate material is necessary (28-30). The materials used in this area were originally stainless steel plates, whereas titanium plates and screws are currently the golden standard.

The successful development of metallic osteosynthesis devices used to stabilize fractured bone fragments was a major impulse for further development of the surgical techniques used to treat dentofacial anomalies. Orthognatic surgery went through a similar develop-

ment for its fixation materials as did cranio-maxillofacial traumatology starting with wire osteosynthesis in combination with IMF to only plate and/or screw fixation and postoperative guiding elastics. With orthognathic surgery osteotomized jaws are put into new positions thus changing facial anatomy and dental occlusion. In a way this can be considered as non-anatomical reposition and fixation of facial fractures, often leaving gaps that are bridged with osteosynthesis plates. The mechanical properties of the fixation materials used for this type of surgery are therefore of utmost importance and can probably not be compared with fracture treatment on a one-to-one ratio.

#### *Characteristics of titanium devices*

Titanium plates and screws are made of pure titanium or titanium alloys. The biocompatibility (31) and the strength of titanium has been thoroughly investigated in many scientific studies. Conventional titanium fixation devices have several disadvantages, which can be summarized as follows:

1. in some patients, particularly those with thin soft tissues, the edges of the inserted (large) plates and screws can be felt. Dehiscence can also occur in situations where the overlying mucosa or skin is very thin. In extreme climates, plates and screws can lead to sensitivity to high or low temperatures;
2. migration and displacement represents the limitation of the use of titanium plates and screws in the growing bones of children or infants;
3. exact bending of the plates is an essential requirement for successful repositioning of the bone fragments. This pre-shaping is time consuming, especially when using voluminous plates;
4. titanium plates and screws interfere with imaging techniques, such as computed tomography and magnetic resonance imaging. The interference with radio-therapeutic treatment techniques is also disadvantageous. The plates and screws can block the radio-therapeutic beam resulting in an inadequate treatment;
5. the most significant disadvantage is probably the continued presence of plates and screws in the human body after the material has fulfilled its function. Despite its biocompatibility, titanium still is a foreign body for the human organism. This generates controversies among experts as to whether implant removal is necessary or not. There is consensus that a follow-up implant removal operation is sometimes indicated (5 - 40%) (32-34), particularly in young patients with growing bone. Implant removal implies an additional surgical procedure with all its associated disadvantages of time, costs, infection risk, discomfort, and anaesthesia.

#### *Characteristics of biodegradable devices*

Since about 4 decades, there is a continuous drive to explore the feasibility of biodegradable devices for the fixation of fractures and osteotomies. The introduction of biodegradable implants can be helpful in eliminating and reducing the disadvantages of titanium plates and screws. Research has revealed that biodegradable materials have limitations as well:

1. most biodegradable plates or meshes must be heated before they can be shaped. The screw holes must be drilled and tapped. This is disadvantageous for difficult and time-consuming craniofacial operations where many plates and screws must be used;
2. low mechanical stability still represents an important issue of the biodegradable systems, particularly when used in load bearing areas such as the mandible;
3. the manufacturers of the biodegradable fixation devices have increased the dimensions due to the low mechanical strength and stiffness of the polymer based fixation devices. The enlarged dimensions could result in difficult wound closure and an increased risk to develop dehiscence;
4. to our best knowledge, there is no definitive evidence that demonstrates that biodegradable (co)polymers can be fully degraded and resorbed by the human body. However, the possible advantage of disappearing fixation devices still seems to be an appealing alternative to fix bone segments in specific situations.

### **AIMS OF THIS THESIS**

The performance of the currently used titanium fixation systems has been thoroughly evaluated. Titanium systems have been proven to be adequate fixation devices except for the disadvantageous aspects mentioned above. Biodegradable fixation devices seem to be an attractive alternative as these systems can reduce or even erase the negative aspects of titanium systems. During the search for the ideal fixation system, the local anatomical circumstances, the forces exerted through the maxillofacial skeleton, as well as the advantages and disadvantages of titanium and biodegradable fixation devices should be taken into account.

The general **aim** of this research project was to establish the effectiveness and safety of biodegradable plates and screws to fix bone segments in the maxillofacial skeleton as a potential alternative to metallic ones.

More specifically, the aims of this research project were:

- to review the currently available scientific evidence for the applicability of biodegradable plates and screws for the fixation of bone segments in the maxillofacial skeleton (chapter 2);
- to establish the torsion strength of titanium and biodegradable fixation screws (chapter 3.1);
- to establish the tensile strength and stiffness, bending stiffness, and torsion stiffness of titanium and biodegradable fixation systems (chapter 3.2.1 and 3.2.2)
- to establish the short term effectiveness and safety (chapter 4) of biodegradable plates and screws used for fixation of fractures and osteotomies in the maxillofacial skeleton compared to conventional titanium plates and screws.